August 3, 2004

Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0264, Federal Measures to Mitigate BSE Risks: Considerations for Further Action

To Whom It May Concern:

The undersigned organizations representing U.S. animal producers, animal food and ingredient processors and manufacturers, meat processors and animal care providers offer these comments to the above-referenced notice.

Our organizations recognize the importance of Bovine Spongiform Encephalopathy (BSE) prevention measures to protect both cattle and public health. We have actively promoted initiatives to manage the potential risk and we have worked closely with the federal government to ensure this country's BSE mitigation efforts include successful, scientifically based animal feeding regulations. Further, in the years prior to 1997, these organizations were active in the development of the feed rule and the other BSE-prevention firewalls, actions that have provided redundant layers of protection of public and animal health. The success of this partnership is illustrated not only by the extraordinarily high industry compliance rate with the current FDA feed rule, but also by the absence of any indigenous BSE cases in the U.S.

A COMBINATION OF RISK MITIGATION OPTIONS SHOULD BE CONSIDERED

We continue to share FDA's commitment to a strong BSE risk control program based on scientific facts and practical justification that can be implemented effectively and consistently. Given our commitment to effective BSE risk management, we are concerned FDA's advanced notice of proposed rulemaking (ANPRM) on BSE mitigation reflects a significant shift in agency philosophy, one that suggests a "one-step cures all" approach and based almost exclusively upon removal of all specified risk materials (SRM) from all animal foods. We are concerned that implementation challenges in this approach may actually limit its effective implementation while causing significant unintended consequences that adversely impact animal health. A careful analysis suggests there may be alternative actions that enable the agency, in concert with industry, to create a system of enhanced feed controls providing equivalent risk mitigation then contemplated in FDA's preliminary conclusion to remove all SRMs from all animal foods.

This combination of risk mitigation steps, evaluating different SRM policy options to reduce potential infectivity in the raw materials moving to rendering, should be coupled with appropriate rendering controls and downstream feed controls to ensure prohibited materials are not fed to ruminants. Prudence dictates FDA must look beyond the feed mill and rendering plant when enhancing surveillance and compliance oversight. This approach is consistent with the findings of the International Review Team, which recommended a system of layered, redundant controls from farm inputs to the consumer.

A RISK/BENEFIT ANALYSIS SHOULD BE CONDUCTED TO EVALUATE VARIOUS OPTIONS

We urge the agency to evaluate an integrated "systems approach" to enhance BSE mitigation. For example, the ANPRM cites the Harvard-Tuskegee Study positing removal of all SRMs from all animal foods may reduce by 88 percent the potential exposure of cattle to BSE when 10 BSE-infected cattle are introduced into the U.S. However, it appears this risk reduction estimate does not fully consider that a more limited SRM removal coupled with the positive effects of rendering on BSE risk reduction, and a high compliance rate with the existing animal feed regulations to prevent prohibited materials from being fed to ruminants, may provide equivalent reduction in exposure.

Risk mitigation measures must be considered in combination, not singularly, when evaluating their risk-reduction potential. And they must be considered in the context of the U.S. experience, where prudent BSE-prevention firewalls, including import controls, active surveillance and feeding restrictions, were implemented seven years or more prior to the first diagnosed case of BSE in North America.

In the context of the systems approach we urge the agency to conduct, if it has not already done so, a formal, rigorous risk/benefit analysis using the accepted USDA model developed by the Harvard Center for Risk Analysis to evaluate the effectiveness of various mitigation strategies. If FDA has conducted their own risk/benefit analysis, we urge that it be released for public review and comment.

A COST/BENEFIT ANALYSIS SHOULD BE CONDUCTED TO EVALUATE VARIOUS OPTIONS

At the same time, the various options available to FDA must be evaluated through an equally rigorous cost/benefit analysis to determine the feasibility, appropriateness, effectiveness of various BSE mitigation techniques, and the opportunity costs and unintended consequences of various actions. If FDA has conducted their own cost/benefit analysis, we urge that it be released for public review and comment. All agree removing all SRMs from animal feed will cause economic dislocation throughout the livestock industry. Such action will likely require redesign of facilities and processes, increase disposal costs, may reduce the value of livestock and may necessitate closure of some facilities that cannot feasibly exclude SRM from their raw material supply. The disposal of SRM and all dead stock will also create significant environmental concerns that are unresolved. The failure of European countries to define an effective SRM disposal system complicated their implementation of feed controls and their prevention of BSE. We believe multiple steps throughout the feed chain should be considered as

part of an integrated systems approach before the agency's proposed rule to ban all SRMs from all animal foods is published.

FDA ACTIONS SHOULD BE BASED ON FINDINGS OF USDA ENHANCED SURVEILLANCE PROGRAM

FDA in 1997 adopted the current feed restrictions based on scientific evidence. The purpose of the ruminant feeding restrictions is to prevent the amplification and spread of the BSE infective agent in the domestic cattle herd. Several scientific studies have reported the risk of BSE in the U.S. is very low, and both USDA and FDA have reaffirmed this finding. Our collective goal is to achieve the greatest degree of potential risk mitigation, at the least cost, and with the greatest compliance.

Recently, USDA greatly expanded its surveillance program to confirm if BSE exists in the U.S. cattle population and to determine its prevalence. This program – an animal disease monitoring program, not a food safety or public health program – has been operational less than 60 days. FDA would be wise to base any prospective actions on the information gathered in USDA's enhanced surveillance program. A clear reading of the International Review Team recommendations supports conducting an aggressive surveillance program to determine which, if any, additional policy actions are appropriate.

CONCLUSION

For each of the aforementioned reasons, we strongly recommend that in place of requiring removal of all SRMs from animal feed, FDA propose a more integrated systems approach that is informed by the results of USDA's enhanced surveillance program and grounded in an appropriate risk/benefit and cost/benefit analysis of various policy options.

FDA is to be commended for its diligence in carrying out its responsibilities to reduce, as much as possible, the risk of BSE in the U.S. We pledge our continued commitment to that goal through regulatory actions based on the best available scientific evidence. Individual coalition members will submit more detailed comments on issues relevant to their memberships.

Thank you for the opportunity to submit these comments to the public record.

Sincerely,

American Feed Industry Association
American Meat Institute
American Sheep Industry Association
National Cattlemen's Beef Association
National Grain and Feed Association
National Meat Association
National Milk Producers Federation
National Renderers Association